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EXAMINER SALMON, KATHERINE D				
ART UNIT		PAPER NUMBER		
1634				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.Docketing@aporter.com

### Office Action Summary

**Application No.**

09/474,435

**Applicant(s)**

CAO ET AL.

**Examiner**

KATHERINE SALMON

**Art Unit**

1634

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2, 6, 12-14, 19-21, 26 and 60-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 6, 12-14, 19-21, 26 and 60-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 11/04/09

#### **DETAILED ACTION**

1. This action is in response to papers filed 11/04/2009
2. Currently Claims 2, 6, 12-14, 19-21, 26, 60-78 are pending. Claims 1, 3-5, 7-11, 15-18, 22-25, and 27-59 have been cancelled.
3. The following rejections are reiterated. Response to arguments follows.
4. This action is being made FINAL.

#### **Withdrawn Objections**

5. The objection to the first paragraph of the specification has been withdrawn based upon further reconsideration and arguments presented in the reply.

#### ***Specification***

6. The amendment filed 4/02/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the specification length limitations as recited in US Patent No. 5608144, 4563417, 60/111990, 09/459109, and 09/459110.

The reply asserts that all of these applications were incorporated by reference in their entireties at the time of filing (p. 12 2<sup>nd</sup> paragraph).

After review of the instant specification, it is noted that 09/459109 and 09/459110 have only been disclosed in the 1<sup>st</sup> paragraph with regard to priority. It is noted that as discussed in the priority section above, the priority to these applications were denied.

Therefore there is no language in the specification which specifically "incorporates by reference".

With regard to application 60/111990, the instant specification on p. 37 lines 10-13 disclosed that "The genomic traces and many of the contigs and singleton traces are disclosed in copending provisional applications for patent identified by serial nos....60111990" . Therefore there is no language in the specification which specifically "incorporates by reference".

With regard to US Patent number 5608144, the instant specification on p. 19 lines 9-10 "additional promoters that may be utilized are described, for example, in US patent Nos. ...5608144...all of which are herein incorporated in their entirety".

With regard to US Patent NO. 4563417, the instant specification on p. 7, lines 11-13 "chemical labels as disclosed in ...US Patent 4,536,417...all of which are incorporated herein by reference to their entirety."

After review of MPEP 608.01(p) [R-3] the mere recitation of these patent applications have not been found sufficient to amend the specification to particular length limitation embodiments.

MPEP states "Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). >37 CFR 1.57(b)(1) limits a proper incorporation by reference (except as provided in 37 CFR 1.57(a)) to instances only where the perfecting words "incorporated by reference" or the root of the words "incorporate" (e.g., incorporating, incorporated) and "reference" (e.g., referencing) appear. The requirement for specific root words will bring greater clarity to the record and provide a bright line test as to where something is being referred to is an incorporation by reference. The Office intends to treat references to documents that do not meet this "bright line" test as noncompliant incorporations by reference and may require correction pursuant to 37 CFR 1.57(g). If a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended.<In addition to other requirements for an application, the referencing application \*must< include an identification of the referenced patent, application, or publication. >See 37 CFR 1.57(b)(2)< Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Guidelines for situations where applicant is permitted to fill in a number for Application No. \_\_\_\_\_ left blank in the application as filed can be found in In re Fouché, 439 F.2d 1237, 169 USPQ 429

(CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending applications; both types are open to the public upon the referencing application issuing as a patent. See >37 CFR 1.14(a)(i)(iv) and (vi) and < MPEP § 103)."

Herein in the instant case, not all the claimed patent application numbers were "incorporated by reference". Further, for the identification of the referenced patent, application, or publication, particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Particularly in the instant case, none of the cited patent applications are found in the section of the instant specification with regard to length limitations. As such the attempt to incorporate particular passages from these patent application and patent documents has been considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

### **Response to Arguments**

The reply traverses the rejection. A summary of the arguments presented in the reply is provided below with response to arguments following.

The reply asserts that for all of the listed US Patent Numbers and US Patent Application Numbers that the specification has clearly indicated that these US Patent Numbers and US Patent Application numbers are incorporated in their entirety (p. 3 of the arguments). The reply asserts that the examiner is arguing that in the instant case, none of the cited patent applications and numbers are found in the section of the instant specification with regard to length limitation (p. 4 1<sup>st</sup> paragraph). The reply asserts this requirement is not supported by law (p. 4 1<sup>st</sup> paragraph). The reply points to law providing for incorporation by reference" for economy, amplification, or clarity of

expression, by means of an incorporating statements clearly identifying the subject matter which is incorporated and where it is to be found" (p. 4 2<sup>nd</sup> paragraph). The reply asserts that the applicants for each of the application numbers and patent numbers have included the root words "incorporate" and "reference" and has stated that the subject matter is the "entirety" (p. 4 2<sup>nd</sup> paragraph). The reply asserts that an analogous example is found in the Federal Circuit noting that when a patent is incorporated in its entirety, the patent become intrinsic evidence to the patents in suit (p. 4 3<sup>rd</sup> full paragraph, the reply citing Systems Division, Inc., v. Teknek LLC).

These arguments have been fully reviewed but have not been found persuasive.

Herein in the instant case, the examiner agrees that the root words "incorporate" and "reference" have been used for each of the cited US Patent Numbers and US Patent Application numbers. The MPEP in 608.01(p) [R-3] indicates that that particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Herein in the instant case, the applicants are attempting to bring in using incorporation by reference essential subject matter to the claims. In all of the US Patent Number and US Patent Application numbers presented above, none of them are recited in the instant specification with regard to guidance for length limitations for nucleic acid fragments. In re de Seversky, as cited by the applicant states, "the incorporation by reference in an application of matter elsewhere written down (not necessarily in a patent application), for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found". In Ex

parte Raille, 8 USPQ2d 1709 (BPAI 1988) it was held that incorporation by reference statement broadly referred to several patent with no specific indication of the relevance of each to the claimed invention and as a result, the amendment was new matter. Herein in the instant case, although these application and patent numbers are recited as incorporated "in their entirety", this is not sufficient to provide a specific indication of the relevance of the recited patent and patent applications to the claimed invention. None of these recited patent and patent applications are described to indicate length limitations of nucleic acids. Further, these applications and patent numbers are recited throughout the specification as referring to other matter in the invention. For example, US Patent 5608144 is recited in the specification on p. 19 describing additional promoters which may be utilized. As such the attempt to incorporate by reference particular length limitations of fragments is improper because there has been no specific indication of the relevance of each to the claimed invention (e.g. the length limitations).

***Claim Rejections - 35 USC § 112/New Matter***

7. Claims 2, 6, 12-14, 19-21, 26, 60-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Based upon the denial of the amendment to the specification provided above, the limitations in the claims with regard to at least 100 contiguous nucleotide residues, at

least 100 contiguous nucleotide residues, and at least about 500 contiguous nucleotide residues have been considered new matter. As the reply to argument specifically claim that these amendments are found in the specification of US patent No. 5608144, 4563517, US Patent application numbers 60/111990, 09459109, and 09459110, these amendments have not been taught in the specification filed 12/28/1999. As stated above, the amendment to the specification (4/02/2009) is considered new matter and as such the amendments to the claims are rejected under 35 USC 112/New Matter.

### **Response to Arguments**

The reply traverses the rejection. A summary of the arguments presented in the reply is provided below with response to arguments following.

The reply asserts that based on the arguments presented for the objection to the specification above, that 35 USC 112/New Matter rejection is moot (p. 5 1st paragraph).

This argument has been fully reviewed but has not been found persuasive.

As stated above, it is the examiner's position that the objection to the specification be maintained and as such the 35 USC 112/New Matter rejection is maintained.



***Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph***

The 35 USC 101 and 35 USC 112/First paragraph set forth below is a reiteration of the rejection set forth in the final rejection mailed 3/18/2008, response to arguments follows.

8. Claims 22, 6, 12-14, 19-21, 26, 60-78 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Claims 2, 6, 12-14, 19-21, 26, 60-78 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22, 6, 12-14, 19-21, 26, 60-78 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to a substantially purified nucleic acid molecules having the sequence of SEQ ID No. 5272, substantially purified nucleic acid molecules comprising fragments of about 100 to 300 nucleotides of SEQ ID No. 5272 and to substantially purified nucleic acid comprising a nucleic acid sequence having at least 98% identity to SEQ ID NO. 5272.

The claimed nucleic acids are not supported by either a specific and substantial asserted utility or a well-established utility.

The specification discloses nucleic acid contig and singleton sequences consisting of SEQ ID Nos 1 to 81,306 were isolated from a library prepared from *Arabidopsis thaliana* ecotype Landsberg erecta tissue (p. 3 lines 17-25 and Example 1). The present claims are limited to nucleic acid comprising SEQ ID NO. 5272 or fragments of SEQ ID NO. 5272 having 98 or 100% identity with SEQ ID No. 5272. The specification does not state whether nucleic acid molecule of SEQ ID NO. 5272 constitutes a complete open reading frame and does not identify the location of the start and stop codons.

The specification also does not set forth a particular biological activity of SEQ ID No. 5272 nor does it describe any protein encoded by SEQ ID No. 5272. Therefore the specification has not established any specific function for SEQ ID No. 5272. Further, there has been no specific use for SEQ ID NO. 5272, The specification asserts the claimed nucleic acids can be used to determine transcriptional profiling to find, identify, and characterize counterpart gene in other species (p. 2 lines 10-15). However, such uses lack a specific and substantial utility. Such uses allow only for the identification and analysis of other nucleic acids. Because a utility has not been established for the present nucleic acid, the use of this nucleic acid to search for additional nucleic acids does not constitute a "real world" context of use.

The specification further contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for mapping studies, linkage analysis, constructing transgenic plants, and screening for traits or screening for polymorphisms (p. 2-3 and 17-18). However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be

used for these purposes. Thereby, these uses are general and do not constitute a specific utility. While the use of the nucleic acid of SEQ ID No. 5272 in the disclosed methods may eventually lead one to the identification of useful traits or specific polymorphisms or may eventually allow for the generation of transgenic plants, such uses constitute further research and experimentation and do not provide a readily-available, specific and substantial real-world use.

The specification also suggests that the proteins encoded by the claimed nucleic acids could be used to generate antibodies, which could be used for detection purposes (p. 16-17). Again, because a utility has not been established for the nucleic acid or the protein encoded thereby, use of the protein to generate antibodies to isolate and study proteins constitutes a research project and does not provide a specific and substantial utility.

The specification further contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for identifying markers and isolate promoters associated with proteins encoded by SEQ ID No. 5272 (15-16). The utility is not specific because it is a property of all plant nucleic acids that they could be used to search for and try to identify a polymorphism or promoter. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. As stated in Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), an invention does not have utility sufficient to satisfy §101 until it is "refined and developed" to the point of providing a specific benefit in currently available form. Id at 534-35, 148 USPQ at 695. In the

instant application, Applicants have not set forth a single promoter or marker, which has been identified using the claimed SEQ ID NO: 5272.

All discussions regarding polymorphisms/markers in the specification are generic in nature. There is no showing of a reasonable expectation that the claimed nucleic acids could in fact be used to identify a specific promoter or marker. Even if a marker could be identified using the claimed SEQ ID NO: 5272, the specification has not disclosed a specific and substantial use for such an uncharacterized marker. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 5272 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of plant. Therefore, the nucleic acids of SEQ ID NO: 5272 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a “real-world” use in currently available form.

The specification asserts that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in microarray as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or

mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific utility. As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined.

The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 5272 or a protein encoded by SEQ ID NO: 5272 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid.

The use of the claimed nucleic acids to detect homologues in other plants and organisms such as alfalfa and barley (p. 21) is also not a substantial and specific utility. Since the functional activity of the presently claimed nucleic acids is unknown, and the functional activity of any putative homologues is unknown, the detection of such homologues does not provide an immediate benefit and serves only as a starting point for further research. In addition, the use of a nucleic acid in a microarray does not confer a patentable utility since all nucleic acids may be used in microarrays. Each of

these asserted utilities are generic, rather than specific. Use of the claimed nucleic acids in the above manners would not be meaningful in the absence of information regarding the specific biological activity or significance of these nucleic acids.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement as it applies to nucleic acids. See In re Fisher 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005). The Court held that 35 USC 101 requires a showing that a nucleic acid is both substantial and specific, stating that "not every 'use' that can be asserted will be sufficient to satisfy §101." The court emphasized that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research." Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." Id. 76 USPQ2d at 1230.

The Fisher Court also held that none of the uses asserted by Applicants in that case were either substantial or specific because each of the "asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." The Court concluded that "granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility."

The instant situation is analogous to that which was addressed in Fisher. In the present case, Applicants have not established that the claimed nucleic acid encodes for a protein with a specific and substantial biological activity, or that the nucleic acid or protein could be used to identify a particular trait or to detect a particular polymorphism or promoter of known function. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

### **Response to Arguments**

The reply traverses the rejection. A summary of the arguments presented in the reply is provided below with response to arguments following.

The reply asserts that the present application has priority to US Provisional Application No. 60/155422 in which the instant SEQ ID No. 5272 is identified as SEQ ID NO. 9911 (p. 5 last paragraph). The reply asserts that in this provisional that SEQ ID No. 5272 was identified as COL2 (see attachment F provided with the 4/2/2009 response and p. 5 last paragraph).

The reply asserts that G1988 (from US Patent Publication 2008/0010703 and differs by one single nucleotides from the corresponding region of SEQ ID No. 5272) and COL2 share greater than 44% homology at the protein level within the zinc finger domain (p. 5 last paragraph).

The reply asserts that it was known at the time of filing that a protein sequence identity even of 20-30% may be used with confident in establishing homologous proteins (p. 5 last paragraph and Brenner et al on IDS). The reply asserts that in the instant case there is a conserved amino acid residues of numerous cysteines which are a common feature among certain classes of zinc finger proteins (p. 5 last paragraph).

The reply asserts that those skilled in the art at the time of filing was aware that COL2 showed significant homology to CONSTANS and that CONSTANS has been identified as a putative zinc finger transcription factor which affects growth (p. 6 1<sup>st</sup> paragraph). The reply asserts that based on sequence identity the skilled artisan would understand that the claimed nucleic acid sequence could be used to affect growth of transgenic plant to alter yield (p. 6 1<sup>st</sup> paragraph).

The reply asserts that therefore the credible utility of the claimed sequence is to modify plants by altering COL2 expression (p. 6 2<sup>nd</sup> paragraph). The reply asserts that there is no legal requirement to set forth a complete open reading frame to establish utility, but rather the law suggests that the specification should disclose a utility such that one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public (p. 6 last paragraph and citation to In re Fischer). The reply asserts that at the time of filing the public was empowered to use the Applications' claimed nucleic acid molecule to produce plants with altered flowering growth and increased yield (p. 6 last paragraph through p. 7 1<sup>st</sup> paragraph).

These arguments have been fully reviewed but have not been found persuasive.



The reply appears to be arguing that based upon the percent identity and description of the sequence in the provisional application 60/155422 the skilled artisan would readily understand that the claimed sequence has functionally homologous to COL2 and therefore have the utility of the CONSTRANS protein family. However, upon review of the specification and the art at the time of filing the examiner's position is that the skilled artisan would not determine that the claimed sequence and COL2 were functional equivalents without post filing research to determine such an association.

The table presented in application 60/155422 (as seen in attachment F of the reply filed 4/02/2009), Describes SEQ ID No. 9911 (e.g. SEQ ID NO. 5272 as claimed) as having a % Identity of 34% and provides a Hit Description of COL2 L81119. Neither the provisional application nor the instant specification provides any further discussion with regard to the relationship of COL2 and SEQ ID No. 5272. Therefore the skilled artisan upon reading the description provided in the specification would be able to determine that there is 34% identity to COL2. The description does not provide that these are functional or structural equivalents.

The reply cites Brenner et al. and asserts that the 44% similarity at the protein level that the claimed sequence shares with the zinc finger domain of COL2 is sufficient for the skilled artisan to determine that these two structures share functional homology. The reply asserts that Brenner et al. (Proc Natl. Acad 1998 VOL. 95 p. 6073 cited on the IDS) teaches that homolog can have 20-30% identity (abstract of Brenner et al.). However, Brenner et al. does not teach that in every case 20-30% structural homology is sufficient for functionality. Brenner et al. teaches that if two proteins show a high

degree of similarity in their structural details and function, it is very probably that they have an evolutionary relationship though their sequence similarity may be low (p. 6074 1<sup>st</sup> column last paragraph-2nd column 1st sentence). Brenner et al. teaches that percentage identity between sequences is a poor measure though there is a rule of thumb stating that 30% identity signifies homolog and that some publications have indicated that 25% identity can be used as a threshold (p. 6076 2<sup>nd</sup> column 1<sup>st</sup> full paragraph). Brenner et al. teaches that there is many pairs of proteins with very different structure that nonetheless have high levels of identity over considerable aligned regions (p. 6076 2<sup>nd</sup> column 1<sup>st</sup> full paragraph). Herein in the instant case the reply asserts that at zinc finger domain region there is 44% identity and therefore this is sufficient based upon the teaching of Brenner et al. to provide utility of the SEQ ID No. 5272 as a functional equivalent of COL2. However, Brenner et al. teaches that there should be similarity in structural details and function. Neither the instant specification nor the art at the time of filing has shown the function of SEQ ID NO. 5272. With regard to structural detail Brenner et al. teaches that a rule of thumb is 30% identity, but that that the percent identity is a poor measure.

With regard to the assertion that 44% identity to a over a particular area is sufficient for functionality to COL2, the examiner's position is based upon the art at the time of filing the skilled artisan would not determine that there is a functional equivalent based upon this structural similarity. Song et al (DNA Research 1998 VOL. 5 p. 95) teaches that the comparison of CONSTANS family in the zinc finger motif that the deduced amino acid sequence similarity is 46-61% similar in the family (abstract).

Therefore the 44% cited is lower than the amino acid comparison at a specific domain structure of the CONSTANS family. Song et al. reviews the zinc finger domain of CONSTANS family, however, the art at the time of filing does not indicate all of the functionally important domain regions. As such the art at the time of filing does not indicate which other changes in the structure would affect functionality. As such although SEQ ID NO. 5272 might share structural identity, the skilled artisan would not know based upon the art at the time of filing if this structure was sufficient for function.

Further, Song et al teaches that the amino acid sequence of 7 putative zinc finger proteins in rice and three known zinc finger proteins in Arabidopsis, including COL2 (p. 99 1st column last paragraph). Song et al. teaches that the amino acid sequence of the zinc finger region of the 7 rice proteins is similar to those of the proteins CO (46-61% identical) (p. 99 1<sup>st</sup> column last paragraph).

Figure 3 of Song et al. provides the alignment of the zinc finger motif (p. 100). The reply based upon the citation of Brenner et al. seems to indicate that the structural identity of 44% at a specific region is sufficient for identity as the functional equivalent of COL2. The reply asserts that among the conserved amino acid residues are numerous cysteines which are a common feature among certain classes of zinc finger proteins (p. 5 last paragraph). Figure 3 of Song et al. indicates that there are 4 cysteine residue regions. In the previous reply of (4/9/2009) the applicant provided an amino acid arrangement of COL2 with G1988 (the structure of SEQ ID NO. 5272 differs by one nucleotide). The reply asserts that there are sufficient conserved amino acid residues to show the zinc finger motif. However, based upon the analysis of the structures

provided, the claimed sequence does not show the 4<sup>th</sup> cytosine residue region. In figure 3, Song et al. indicates that COL2 (which is the same GenBank accession number recited in the provisional application as having 33% identity to SEQ ID NO. 5272) has 4 cysteine motifs. These appear at positions 16, 19 (residue structure 1), 36, 39 (residue structure 2), 59, 62 (residue structure 3) and 79, 82 (residue structure 4). As shown in the alignment of attachment F, the amino acid structure of G1988 does not show any alignment to positions 79, 82 of COL2. As shown in figure 3 of Song et al. this 4<sup>th</sup> cysteine residue structure is observed in all other amino acid sequences including CONSTANS, COL2, STO, NTL1 of tobacco, hGATA-1 of human, mGATA-1 of mouse, and cGATA-1 of chicken. As such although Brenner teaches that the structure does not have to be high between functional proteins, the art at the time of filing indicates that the claimed sequence does not have a sufficient conserved amino acid residue structure that would be a common feature of zinc finger proteins of this family.

As such the art at the time of filing and the description in the specification are not sufficient to provide the skilled artisan with a claimed discovery which can provide some "immediate benefit to the public". Wherein it is the examiner's position that upon reading the description provided in the instant specification in view of the art at the time of the filing, the skilled artisan would not readily give the utility of a COL2 functional equivalent to SEQ ID No. 5272.

***Claim Rejections - 35 USC § 112/Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 12-14, 19-21, 26, 60-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

**Response to Arguments**

The reply traverses the rejection. A summary of the arguments presented in the reply is set forth below with response to arguments following.

The reply asserts that the enablement rejection has been overcome by the forgoing arguments regarding utility (p. 7 last paragraph).

These arguments have been fully reviewed but have not been found persuasive.

As indicated above, the instantly claimed invention still has not overcome the issues concerning specific and substantial utility and as such both the 35 USC 101 rejection and the 35 USC 112/Enablement rejections have been maintained.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday - Friday 9AM-530PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon

/Sarae Bausch/  
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